Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed April 26, 2011. Currently, claims 1, 3-10, 12-21, and 23-31 remain pending. Claims 1, 3-10, 12-21, and 23-31 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 14-16, 19, 20, and 27-29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (U.S. Patent No. 5,421,955), hereinafter Lau, in view of Stack et al. (U.S. Patent No. 6,264,683), hereinafter Stack. After careful review, Applicant must respectfully traverse this rejection.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03.) As discussed previously, the combined disclosures of Lau and Stack are insufficient to overcome the deficiencies of Lashinski (U.S. Patent No. 6,579,305). Here, the Examiner relies only upon Lau in view of Stack although a significant portion of the Examiner's argument appears to rely instead upon an uncited reference, Kasprzyk et al. (U. S. Patent No. 5,114,423). Nevertheless Applicants will attempt to further prosecution by treating the Kasprzyk reference as though it had been cited as a secondary reference in the §103 rejection. Appropriate clarification and/or correction are respectfully requested in a future non-final Office Action.

The primary reference Lau, apparently directed to expandable stents and methods of making them, is asserted to provide a stent delivery system with particular reference to Figs. 1-3 which do not appear to disclose the structural elements of a stent delivery system upon which the Examiner relies. Specifically, the delivery catheter of Lau does not appear to disclose an inner tube disposed within an outer tube or a distal tip associated with an inner tube.

Examination of Figs. 1 and 2 of Lau appears to show that the distal end of an inner shaft, not illustrated and present only by inference, is smaller in outer diameter than

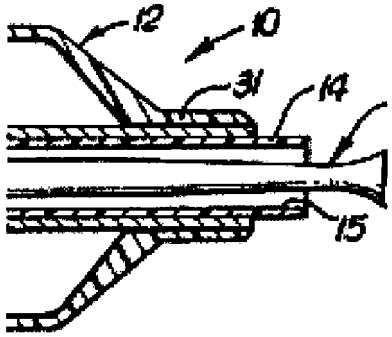
the distal end of the balloon of delivery catheter 11 which must surround it. Accordingly, a putative distal tip which might define an edge diameter must fit within the balloon and so must be smaller than the balloon which contains it. Similarly catheter 11 of Figs. 1 and 2, which appears to most nearly correspond to an outer tube, is also smaller than the proximal end of balloon 14 which surrounds it. Accordingly, the distal end of catheter 11 appears to be smaller than the balloon 14 which surrounds it and thus the distal end diameter of the distal end of the catheter 11 appears to be less than the diameter of the balloon 14 about which the unexpanded stent 10 is crimped. Using the most generous dimensions inferable from Fig. 1, the "maximum outer diameter of the stent in an unexpanded form", located within the inner diameter of the delivery sleeve 20, appears to be at least 1.8 times greater than the edge diameter and at least 1.3 times greater than the distal end diameter as those terms are defined in the current specification and claims. Accordingly, the delivery system of Lau does not appear to teach "wherein the edge diameter and distal end diameter are equal to or greater than a maximum outer diameter of the stent in an unexpanded form" as recited in claims 14 and 27.

The method of use disclosed by Lau at col. 4, line 53 to col. 5, line 6 does not appear to teach heating the stent to expand the stent, deflating the balloon, or withdrawing the inner and outer tubes and balloon from the vasculature. Instead, Lau appears to rely upon an inflatable balloon and appears to be silent with regard to steps of deflating and removing apparatus comprising inner and outer tubes and a balloon. Heating appears to be mentioned only in the instance of a thermoplastic stent which may be softened by heating allowing the softened stent to be expanded. The expansion, which apparently is facilitated by heating, appears to result directly from inflation of the balloon rather than by the heating of the stent. The Examiner turns to a reference, Kasprzyk, not cited directly in the rejection but instead incorporated by reference by Lau in an effort to overcome deficiencies of Lau.

Kasprzyk appears to teach an alternate method of warming an inflation fluid within a balloon to soften a plastic stent to facilitate the expansion thereof upon inflation of the balloon, the context in which the reference appears in Lau at col. 6, lines 45-56, and as in Lau, the expansion of the stent appears to be the result of balloon inflation

rather than heating of the stent. Heating of the stent appears only to soften the stent, but not to expand it.

Kasprzyk is further asserted to disclose an inner tube 14 having a distal tip identified by reference numeral 31 in Fig. 1 of Kasprzyk and identified therein as "shoulder 31 of balloon 12" (col. 5, line 33.) Balloon 12 is disposed about and proximal of the distal end of inner tube 14 which passes through the lumen of balloon 12 and extends distally beyond the balloon. Additionally, inner conductive layer 26 (identified in a more proximal portion of Fig. 1) is described and illustrated as located between balloon 12 shoulder 31 and inner tubular member 14 as are optional insulating layers not shown. Further Kasprzyk explicitly describes balloon 12, of which shoulder 31 is a part, as "biaxially oriented polyethylene terephthalate" while the "inner tubular member 14 is formed of polyimide tubing" thereby differentiating the balloon 12 and the inner tubular member 14 of Kasprzyk both structurally and compositionally. (Col. 6, lines 5-8.) The composition of intervening inner conductive layer 26 does not appear to have been identified. Accordingly, proximally displaced balloon shoulder 31 is neither a distal tip of inner tube 14 nor any other component of the inner tube 14 as will be seen in the detail of Fig. 1 reproduced below for convenience.



Attention is drawn to the diameter of the inner tubular member which appears to be uniform throughout the portions of Fig. 1 in which it appears. Accordingly, the distal edge diameter associated with the inner tubular member appears to be identically equal to the diameter of inner tubular member 14.

Even were one to accept the Examiner's assertion that shoulder 31 of balloon 12 provides a distal tip, which Applicants do not, the proximal edge of shoulder 31 at the proximal-most extent of the contact of shoulder 31 with inner conductive layer 26 is significantly smaller than the diameter of the balloon 12 which the Examiner appears to

equate with the unexpanded balloon of the delivery device of Fig. 1 of Lau. Attention is directed to the relative outer dimensions of the balloon 12 of Kasprzyk and the elements 26 and 14 thereof. The outer diameter of the uninflated balloon of the delivery device of Kasprzyk appears to be either 2.8 or 3.6 times distal edge diameter defined by those elements respectively. Although Kasprzyk does not illustrate a stent disposed about the heated catheter, or indeed even to mention a stent, were a stent to be disposed about the exterior working surface 23 of balloon 12, the stent's maximum outer diameter in an unexpanded form would necessarily appear to be greater than the inner diameter which would correspond, at a minimum, to that of the exterior working surface 23 of balloon 12 and thus the stent's maximum outer diameter would appear to be even greater than the ratios indicated above for the diameter of the balloon.

The annular lumen of Kasprzyk, to which the Examiner makes reference, appears to be defined by the inner wall of tubular member 11 and the outer surface of coaxial cable 24. Thus while inner tubular member 14 is contained within coaxial cable 24 and so within the lumen of outer tubular member 11, one of ordinary skill in the art would not, absent further disclosure, construe the annular lumen 32 to be "an annular space between the inner tube and the outer tube in that a significant fraction of that space is occupied by the coaxial cable 24.

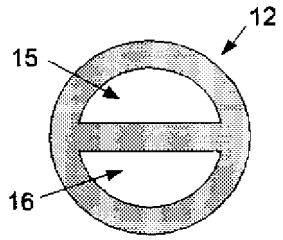
Returning to the Examiner's analysis of Lau, Applicants note the assertion that "(it is inherent that the balloon would be deflated and the catheter withdrawn from the vasculature after the stent is delivered to its desired site)." Applicants respectfully disagree. While deflation prior to removal may be common in such circumstances, it is by no means necessary or inherent in all circumstances. As described by Lau, heating may "facilitate the expansion of the stent" (col. 6, line 48), but does not appear necessarily to be responsible for the expansion as witnessed by the utility of employing a protective delivery sleeve 20 as a means of ensuring that the stent stays in place on the expandable portion of the delivery catheter and further by Lau's apparent reliance upon the superelastic property of a NiTi alloy in some embodiments.

Even were the I.D. of the expanded stent to be the same as the O.D. of the balloon, there appears to be nothing in the disclosure of Lau which indicates that the balloon must necessarily frictionally engage the stent to an extent which would prevent

withdrawal of the inflated balloon from the stent. Lau appears to contemplate the possibility that the stent would be readily displaceable along the surface of the balloon by noting that a protective sleeve 20 may be used to ensure that the stent remains in place on the balloon (col. 4, lines 36-41 and appears to teach that the balloon may be tapered which may allow it to be withdrawn from the stent (col. 4, lines 49-52) with little or no displacement force.

As acknowledged by the Examiner, "Lau does not explicitly disclose that the edge diameter of the tapered distal tip of the inner tube and the distal end diameter of the outer tube are equal to or greater than a maximum outer diameter of the stent in an unexpanded form" and as discussed above appears explicitly to teach the opposite relationships among the respective diameters thereby teaching away from the arrangement of the current invention although not actively disparaging the necessary modifications.

Turning to Stack, the Examiner asserts that second stent bumper 20 of Stack provides a tapered distal tip of an inner tube. As discussed previously in the Pre-appeal Brief filed December 21, 2010 which resulted in prosecution being reopened, Stack does not appear to disclose a first outer tube and a second inner tube, but rather appears to disclose a single catheter 10 comprising shaft 12 having two adjacent lumens, inflation lumen 15, which extends to a proximal end of a balloon, and guidewire lumen 16, which extends through the balloon. (See col. 2, lines 49-52.) However, one of ordinary skill in the art would not consider the dual lumen shaft of Stack to comprise inner and outer tubes, the inner tube being disposed within the outer tube, as required by the claims. Indeed, the putative inner and outer "tubes" asserted by the Examiner at best appear to be two lumens which share a common wall within shaft 12. (See below and note the absence of tubular structures visible in the break between the proximal and distal sections of shaft 12 in Figs. 1-4.) Furthermore, Stack does not appear to disclose two tubes arranged, concentrically or otherwise, so as to form an annular space between them, as required by the claims.



Accordingly, bumper 20 of Stack, attached proximate a distal end of single shaft 12 does not appear to disclose a distal tip of an inner tube, neither lumen of Stack being identifiable as an inner tube.

As discussed above, Lau in view of Stack and/or Lau in view of Kasprzyk and Stack does not appear to teach all limitations of the methods of independent claims 14 and 27, as is required to establish a *prima facie* case of obviousness. Applicants respectfully request that the rejections be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claims 15-16, 19, 20, and 28-29, which depend from nonobvious independent claims 14 and 27 respectively, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

Claims 1, 3-9, 12, 13, and 23-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lau in view of Stack and further in view of Lashinski (U.S. Patent No. 6,579,305). After careful review, Applicant must respectfully traverse this rejection.

As discussed above, Lau in view of Stack does not appear to teach the mechanical components of the pending claims, specifically:

> "an inner tube comprising a proximal end, a distal end, and a lumen extending therebetween, the inner tube being disposed within an outer tube with an annular space disposed therebetween, the distal end of the inner tube further comprising a distal tip having a proximal edge defining an edge diameter ... the distal end of the outer tube being disposed proximally to the distal tip of the inner tube and defining a distal end diameter ... wherein the edge diameter and distal end diameter are equal to or greater than a maximum outer diameter of the stent in an unexpanded form; wherein the annular space is not in fluid communication with the lumen of the inner tube and an exterior of the balloon"

As discussed in detail earlier in prosecution, in the Pre-appeal Brief of December 21, 2010, and as acknowledged by the Examiner in the final Office Action of July 12, 2010, Lashinski, as a primary reference supplemented by Lau and Stack, does not appear to teach all of the components of the apparatus of the pending claims, their form, and

arrangement. In the current Office Action, the Examiner appears to rely upon Lashinski solely to provide a stent formed of shape memory material. Accordingly, Lashinski does not appear to overcome the structural deficiencies of Lau discussed above, with or without Stack. Lau (and uncited Kasprzyk) in view of Stack and Lashinski does not appear to teach all limitations of independent claims 1 and 23, as is required to establish a *prima facie* case of obviousness. Applicants respectfully request that the rejections be withdrawn.

Accordingly, claims 3-9, 12, 13, and 24-26, which depend from nonobvious independent claims 1 and 23 respectively, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

Claim 10 was rejected under 35 U.S.C. 103(a) as being unpatentable over Lau in view of Stack and Lashinski and further in view of Fischell et al. (U.S. Patent No. 5,976,153), hereinafter Fischell. After careful review, Applicant must respectfully traverse this rejection.

As discussed above, claim 1 is believed to be nonobvious over Lau (uncited Kasprzyk), Stack, and Lashinski. Fischell has been asserted to teach a radiopaque marker; however a radiopaque marker is not a limitation of independent claim 1 and so Fischell does not appear to overcome the deficiencies of Lau (uncited Kasprzyk), Stack, and Lashinski as applied to nonobvious independent claim 1. Claim 10, which depends from nonobvious independent claim 1, also is believed to be nonobvious and Applicants respectfully request that the rejection be withdrawn.

Claims 17, 18, and 30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lau in view of Stack, as applied to claims 14, 16, and 27 above, and further in view of Rabkin et al. (U.S. Patent No. 6,676,692), hereinafter Rabkin. After careful review, Applicant must respectfully traverse this rejection.

As discussed above, Lau in view of Stack does not appear to teach all limitations of independent claims 14 and 27, as is required to establish a *prima facie* case of obviousness. The addition of the teaching of Rabkin, asserted to teach the use of a warm saline solution for heating the stent, a limitation not found in either claim 14 or 27, does

not appear to overcome the deficiencies of those references as applied to independent claims 14 and/or 27. Claims 17, 18, and 30, which depend from nonobvious independent claims 14 and 27 respectively, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

Claims 21 and 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lau in view of Stack, as applied to claims 19 and 27 above, and further in view of Healy et al. (U.S. Patent No. 6,607,553), hereinafter Healy. After careful review, Applicant must respectfully traverse this rejection.

As discussed above, Lau in view of Stack does not appear to teach all limitations of independent claims 14 and 27, as is required to establish a *prima facie* case of obviousness. The addition of the teaching of Healy, asserted to teach the use of a thermocouple not found in either independent claim 14 or 27, does not appear to overcome the deficiencies of those references as applied to independent claims 14 and/or 27. Claims 21 and 31, which depend from nonobvious independent claims 14 and 27 respectively, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: July 11, 2011

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